"FREQUENTLY ASKED QUESTIONS" (FAQs) FOR LABORATORIES REGARDING HUMAN IMMUNODEFICIENCY VIRUS (HIV) REPORTING REGULATIONS IN CALIFORNIA

Q1. Can the State Office of AIDS (OA) develop a comprehensive list of HIV-related tests that laboratories can use to screen for HIV reporting?

Ans: No, the OA will not develop such a list. Technicians/microbiologists in each laboratory should be able to compile a list of their own as the regulations describe what constitutes a reportable test. As new technology and new tests come onto the market, laboratories will be the first to know which new tests are subject to the reporting requirements, and will be able to update their lists accordingly.

Q2. Are undetectable viral load test results reportable?

Ans: Yes, all HIV RNA (viral load) tests are reportable. Ordinarily, a health care provider will request viral load tests only for patients known to be HIV positive.

To meet the minimum performance standards set forth by the Centers for Disease Control and Prevention (CDC), the OA must ensure that the State's HIV/AIDS surveillance system captures data for at least 85% of all HIV-infected individuals in California, regardless of their viral load status.

Q3. Are results of ELISA, CD4, or drug resistance tests reportable by laboratories?

Ans: No, laboratories are NOT required to report findings for the following tests to the local health departments:

- ELISA or EIA (used for initial screening, a positive test result is not conclusive);
- CD4 or CD4:CD8 ratio (used for measuring the number of T-helper cells or T-helper and T-suppressor ratio, not for detecting HIV);
- Drug resistance tests (genotypic / phenotypic tests are used for determining if a person's virus is likely to be suppressed by a specific anti-HIV drug, not for the presence of HIV).

Q4. Why are results of drug resistance tests not reportable?

Ans: Drug resistance tests show whether a person's virus is likely to be suppressed by a specific anti-HIV drug, not the presence of HIV. Genotypic/phenotypic tests are typically ordered simultaneously with viral load tests. Since all viral load tests are reportable, reporting tests done for drug resistance would be duplicative and burdensome for the laboratories, health care providers and local health departments.

Q5. If an HIV test includes multiple component tests, for instance, the Western blot tests for the presence of several types of proteins (p24, gp41, p55, gp120, gp160), should the laboratory report each component test result to the local health department if a confirmed test is determined?

Ans: If an HIV test is comprised of multiple component tests and the final serologic interpretation of the test is based on certain established criteria, laboratories should NOT report each component test result to the local health department. The local health department only needs the final serologic interpretation of the test.

Q6. When more than one laboratory is involved in the testing of the specimen, which laboratory is responsible for reporting the confirmed HIV test result to the local health department?

Ans: Under the HIV reporting regulations, the reporting responsibility falls onto the laboratory that first receives the biological specimen from the health care provider. The OA recognizes that this is a slightly different process than for other reportable conditions such as gonorrhea, hepatitis A or B, malaria, tuberculosis, etc.

Q7. If a laboratory only draws the biological specimen from the client, but forwards the specimen to another laboratory for testing, is it still responsible for reporting to the local health department if a confirmed HIV test is determined?

Ans: Yes. The regulations specifically states that the laboratory that first receives the biological specimen shall report confirmed HIV tests to the local health department.

Q8. If a laboratory transfers the specimen to another laboratory (reference laboratory) for testing, it may not know the date the specimen was tested at the reference laboratory. Since the laboratory that first receives the specimen has the responsibility to report, what should they do?

Ans: If possible, the laboratory should obtain the date from the reference laboratory. Otherwise, it should report, as an alternative, the date on which the test result was released to the health care provider by the laboratory that first received the specimen.

Q9. What happens if the reference laboratory reports results directly to the health care provider and not back to the laboratory that first receives the specimen?

Ans: The laboratory that first receives the specimen is responsible to ensure that tests subject to the regulations are reported to the appropriate local health department within 7 calendar days of determining a confirmed result. The OA suggests that laboratories establish collaborative relationships with each other and develop protocols by which the reporting requirements can be met.

Q10. To which local health department should the report go and to whom at the local health department should the reports be sent?

Ans: The report should go to the local health department for the jurisdiction where the health care provider facility is located. Contact information for HIV/AIDS surveillance staff at the 61 local health departments is available on the OA website www.dhs.ca.gov/aids. Reports should be sent to the individual whose name is marked with an asterisk.

A question has been posted: Suppose a physician whose office is located in Los Angeles County also works in a clinic located in Long Beach. He/she orders an HIV test for a client from the Long Beach clinic. If the laboratory determines a confirmed HIV test, which health department should the laboratory report the result to, Los Angeles County or City of Long Beach Health Department? The report should be forwarded to the City of Long Beach Health Department.

Q11. Why are there 61 local health departments, not 58?

Ans: In addition to the 58 counties, the cities of Long Beach, Pasadena, and Berkeley are separate health jurisdictions and have their own health departments.

Q12. Based on the health care provider facility's city and zip code, how can laboratories determine to which county/city health department should the reports be sent?

Ans: The OA recommends that laboratories use the same method that they currently use to determine the health jurisdiction where the health care provider's facility is located for other reportable conditions such as tuberculosis, gonorrhea, and so on.

For laboratories that wish to report electronically, laboratory information technology (IT) staff or programmers may have to develop computer algorithms to determine county where the health care provider's facility is located based on city and/or zip code. The following website, http://www.getzips.com/zip.htm may provide some assistance.

Q13. Should a California laboratory report a confirmed HIV test result if the biological specimen came from an out-of-state laboratory or health care provider?

Ans: Yes. However the confirmed HIV test result should be reported to the state health department in the state where the biological specimen originated.

Q14. How should laboratories report confirmed HIV test results to the local health departments?

Ans: There is no mandate on how confirmed HIV test results should be reported to the local health departments. However, in an effort to assist laboratories and local health departments to develop an efficient reporting system, the OA has devised a standardized paper-based reporting form as well as reporting formats and coding vocabularies for electronic reporting.

The standardized paper-based reporting form can be found on the OA website www.dhs.ca.gov/aids.

For laboratories that have the IT infrastructure and capability to report test results electronically, the OA highly encourages you to do so in lieu of the paper-based system, as electronic reporting is likely to be more complete, accurate and timely. An automated and streamlined reporting process will also reduce staffing time for filling out the paper forms at laboratories and for manual data re-entry at local health departments. You may contact the HIV/AIDS surveillance unit of your local health department for a copy of the OA's *Instructions for Submitting Confirmed Human Immunodeficiency Virus (HIV) Test Results Electronically by Laboratory to Local Health Department*.

Q15. Can laboratory paper-based reports be faxed? Can electronic reports be sent as attachments of e-mails or do they have to be sent via postal mail on diskettes/CDs?

Ans: Since neither the paper nor electronic report contains identifying information of the patient, laboratories may send paper-based reports via postal mail, or facsimile to the local health department's confidential fax line. Electronic files may also be sent as attachments of e-mails, provided that the local HIV/AIDS surveillance staff is able to receive e-mail.

Q16. Should laboratories password protect or encrypt electronic files that are sent to the local health departments?

Ans: The OA is not requiring laboratories to password protect or encrypt electronic report files, as the files contain no patient identifying information. However, if laboratory staff believe that certain laboratory information (such as the accession number) can be used to identify an individual, OA encourages laboratories to make arrangements with each local health department to password protect or encrypt their electronic reports.

Q17. Are all local health departments able to receive electronic reports of confirmed HIV tests from laboratories?

Ans: No, not all local health department HIV/AIDS surveillance staff have the ability or knowledge to process electronic laboratory reports, and that is why a standardized laboratory paper-based report form was also developed for manual reporting to local health departments. The paper-based report form can be found at the OA website www.dhs.ca.gov/aids. The OA is currently developing computer programs to assist local health departments in handling and managing electronic laboratory reports.

Q18. What if the electronic file does not fit on a single 3.5" diskette?

Ans: This issue should seldom come up since laboratories are required to report within 7 calendar days of determining a confirmed HIV test. However, if it should happen, the OA recommends that laboratories use a self-extracting compression software package such as WinZip that has the option to span to multiple diskettes if necessary.

Q19. What should a laboratory do if it receives incomplete patient data from a health care provider for a biological specimen with a confirmed HIV test?

Ans: The regulations require the laboratory to contact the submitting health care provider to obtain the missing information prior to reporting the confirmed test result to the local health department.

Q20. When a laboratory receives incomplete patient data from a health care provider for a biological specimen with a confirmed HIV test, following up with the health care provider may take longer than 7 calendar days. What should the laboratory do in this situation?

Ans: Laboratories should proceed to report the confirmed test result to the appropriate local health department within the time specified by the regulations. Any new patient data obtained after the 7-calendar-day period should be reported to the local health department as an update under the same accession number. If the new data is sent electronically using the format specified by the OA, Field #32 (UPDT_FLAG) should be recorded as "1" to indicate that the record is an update of a previously reported test result with missing or incorrect data.

Q21. How can I get software to produce the soundex portion of the Partial Non-Name Code?

Ans: You may go to the OA website www.dhs.ca.gov/aids to download the OA approved soundexing programs. The programs are in DOS, Windows, Access, Excel, SAS, and JavaScript. Any other soundexing programs available on the Internet or elsewhere are not authorized for HIV reporting procedures.

Q22. If a health care provider submits to the laboratory only a code for the patient instead of name or surname (for example, prison inmate number), what should laboratories do?

Ans: Since the laboratory is required to generate the soundex code for a confirmed HIV test, the laboratory should contact the health care provider to obtain the patient's surname. If the health care provider does not wish to release the patient's surname, ask if he or she could generate the soundex code and provide the code to the laboratory.

If the health care provider will not release the patient's surname or soundex code, laboratories should NOT convert the patient code into a soundex code. Instead, the soundex code should be recorded as missing (blank on laboratory paper-based report form and a single period "." in

electronic report), and the patient code should be recorded in the box labeled PATIENT CODE # on the laboratory paper-based report form or in Field # 6 (CODE_BY_PVD) on the electronic report. The local health department will then follow-up with the health care provider to obtain the soundex code of the patient.

Q23. Do laboratories need to generate a partial non-name code for every HIV test?

Ans: No. Laboratories only need to generate partial non-name codes for confirmed HIV tests, as defined by the regulations.

Q24. What if the laboratory data system does not accept a value of "3" or "4" for gender to indicate the specimen came from a transgendered individual?

Ans: The OA is aware that, at present, health care providers generally do not record on laboratory requisition forms if the specimen came from an individual who is a transgender. Therefore laboratory data systems may not have such information or the systems may not allow any value other than "M" for male, "F" for female, or "U" for unknown. We are recommending laboratories to report "gender" to local health departments using the following rules:

"1" if gender is "Male" or "M" in the laboratory database
"2" if gender is "Female" or "F" in the laboratory database
"." if gender is "Unknown", "Missing", or "U" in the laboratory database

The regulations require health care providers to record transgender information on laboratory requisition forms when ordering HIV-related tests, i.e., using "3" for transgender male-female or "4" for transgender female-male. The OA recognizes that it may take some time for this new procedure to become standard practice. If your system will not accept a value of "3" or "4", you should record gender as the person's gender at birth. That is to say, "3" should be recorded as "Male" or "M" and "4" should be recorded as "Female" or "F" in your database, and then follow the rules above when reporting to the local health departments.

Q25. Are laboratories responsible for keeping track of who has been reported to the local health department?

Ans: No. Laboratories are required to report all confirmed HIV tests to the local health departments, regardless of whether or not the laboratory has previously submitted a report for a patient.

Q26. In the instruction for electronic reporting, Field #21-25 asks for provider's address and phone number and Field #27-31 ask for address and phone number of the facility that submitted the specimen. What should laboratories do if only one address/phone number is given?

Ans: Put the address and phone number information in the appropriate fields and leave the others as missing, i.e., a single period ".". The regulations only require information to be provided in Field #27-31 if it is different than information provided in Field #21-25.

Q27. Can CLIA number be less than 15 digits?

Ans: Yes. Report CLIA number as it is assigned to the laboratory, regardless of whether it is 15 digits in length.

Q28. What is a "Laboratory report number as assigned by the laboratory"?

Ans: The laboratory report number as assigned by the laboratory refers to the specimen accession number or other unique specimen identifier assigned by the laboratory.

Q29. Laboratories do not usually report accession numbers to the health care provider.

Ans: To facilitate case report matching by the local health departments, laboratories should begin to report accession numbers for all confirmed HIV tests to the health care provider. The OA recommends that the accession number be clearly labeled and recorded on the laboratory report sent back to the health care provider.

Q30. How would a laboratory know if a specimen comes from an individual who is participating in a blinded and/or unlinked seroprevalence study?

Ans: The OA understands that it is not reasonable to expect laboratories to follow-up on each confirmed HIV test to determine if the specimen came from an individual who is participating in a blinded and/or unlinked seroprevalence study. Therefore, it is suggested that laboratories report all confirmed HIV tests to local health departments unless the laboratory has specific knowledge that the individual is a participant of an exempted blinded and/or unlinked seroprevalence study.

Q31. Who is going to pay the laboratories to do the reporting?

Ans: Reporting of confirmed HIV tests is mandated by California regulations and, as with all other reportable diseases, is not reimbursable.

Q32. What happens to a laboratory if it does not comply with the regulations?

Ans: It is possible that persons who willfully neglect or refuse to report in accordance with the HIV reporting regulations may be found guilty of a misdemeanor under Health and Safety Code section 100182 and may be subject to prosecution.